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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/374,213

08/13/1999

DAVID STERN

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3469

7590

09/14/2006

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/374,213	Applicant(s) STERN ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41, 44, 46, 55-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 44, 46 and 55-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. This application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid.

The amendment filed 13 May 2006 has been entered. Claims 1-40, 42, 43, 45 and 47-54 were previously cancelled by Applicants. Claims 59 and 60 have been added.

It is noted that priority information has been deleted from this application by the amendment filed 28 April 2006. The effective filing date for this application is now 13 August 1999.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41, 44, 46 and 55-60 are currently under examination.

Claim Rejections/Objections

Claim objections

Claim 55 is objected to for reciting or encompassing non-elected inventions - e.g., "a bone marrow cell."

Claim Rejections: Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 44, 46, and 55-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, 14, 15, 49, 50, 52, 53, 56-66 and 68 of Patent Application No. 08/592,070. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Instant claims 41, 44, 46, and 55-60 are drawn to a method of inhibiting binding of a beta-sheet fibril to RAGE on the surface of a cell, by administering an inhibitory compound. Claims 1, 2, 14, 15, 49, 50, 52, 53, 56-66 and 68 of the '070 Application are drawn to a method for inhibiting binding of beta-amyloid 1-40 and 1-42 with RAGE on the surface of a cell by adding sRAGE.

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The instantly claimed method is an obvious variation of the claims as set forth in the '070 Application because as disclosed in the instant specification (p. 2, line 24), beta-sheet fibrils include amyloid-beta peptides, of a variety of lengths, including amyloid-beta peptides 1-40 and 1-42. In addition, "a compound that inhibits binding of the beta-sheet fibril to RAGE" is defined as including sRAGE or a fragment thereof (p. 25, line 13). Instant claims 41, 44, 46, and 55-60, by adding the requirement of a "beta-sheet fibril" and "a compound" in addition to sRAGE, are obvious over Claims 1, 2, 14, 15, 49, 50, 52, 53, 56-66 and 68 of the '070 Application because they merely change the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections- 35 USC § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 44, 46, and 55-60 are rejected under 35 U.S.C. 102(b) as being unpatentable over Stern, et al, 1997 (WO 97/26913). Stern, et al disclose methods of inhibiting the interaction of amyloid peptides with RAGE on the surface of cells, identical to the methods disclosed in the instant application. This reference meets the

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limitations of claims 41, 44, 46, and 55-60 of a method of inhibiting binding of "beta-sheet fibril" to RAGE on the surface of cells.

Claims 41, 44, 46, and 55-59 are also rejected under 35 U.S.C. 102(b) as being unpatentable over Morser, M.J., 1997 (WO 97/39121). The claims are directed to a method of inhibiting binding of beta-sheet fibrils to RAGE on the surface of a cell using a variety of inhibitory compounds. The publication discloses a method for inhibiting interactions between RAGE and compounds that bind RAGE, such as AGE's, Tau and amyloid beta-peptides. It also discloses compositions, including sRAGE, that are capable of inhibiting an interaction between RAGE and ligands, thus anticipating Claims 41, 44, 46, 56 and 59. It primarily discusses how such compositions may be used to reduce the pathological effects of diabetes, occlusive vascular disorders, and Alzheimer's disease (p. 26), but it also gives several binding assays in which binding of peptides to RAGE was inhibited by sRAGE or amyloid fibrils. It also contemplates binding interactions on cells that express RAGE (p. 23-25), which include endothelial cells and phagocytes, thus anticipating Claim 55. It also contemplates inhibiting the binding of AGE's (which include beta-fibrils) with RAGE outside the central nervous system (Figure 14B), thus anticipating Claims 57 and 58.

The publication does not anticipate use of the V-domain of sRAGE, as recited in Claim 60.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morser, M.J., 1997 (WO 97/39121), applied to Claims 41, 44, 46, and 55-59 above, and further in view of Schmidt, et al, (2002, US Patent 6,465,422). Schmidt, et al discuss administration of the V-domain of RAGE for pharmaceutical purposes (see column 8) including inhibiting tumor invasion and including modified species of the V-domain. Thus, it would be obvious to use the V-domain of RAGE as an inhibitory ligand of RAGE, much in the same way as other inhibitory fragments recited in Claims 41, 44, 46, and 55-59.

35 USC § 112, second paragraph-indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 44, 46 and 55-60 are rejected under 35 U.S.C. 112, -second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims encompass a method of using B-fibrils, sRAGE and other compounds for inhibiting the interaction of an amyloid-like peptide with RAGE. However, one skilled in the art cannot determine the metes and

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bounds of the claimed invention because there is no recognized structural or functional determinants in the claims such that the molecules encompassed can be distinguished from any other molecule. Aside from the art-recognized names of the molecules used for the claimed invention, such as *B-sheet fibrils* and *RAGE*, there is nothing to distinguish them from similar peptides from other species, nor from mutants and variants.

Conclusion:

Claims 41, 44, 46 and 55-60 are rejected for the reasons cited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM

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(Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

9 September 2006


EILEEN B. O'HARA
PRIMARY EXAMINER